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10/584,739	06/26/2006	Yoshiaki Hashimoto	KUZ0032US.NP	5791
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EXAMINER				
ORWIG, KEVIN S				
ART UNIT		PAPER NUMBER		
1611				
NOTIFICATION DATE		DELIVERY MODE		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/584,739

Applicant(s)

HASHIMOTO ET AL.

Examiner

Kevin S. Orwig

Art Unit

1611

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SF 298)
Paper No(s)/Mail Date 8/3/06
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____

DETAILED ACTION

Status of the Claims

Claims 1-11 are currently pending and are the subject of this Office Action. This is the first Office Action on the merits of the claims.

Priority

The earliest effective U.S. filing date afforded the instantly claimed invention has been determined to be Dec. 24, 2004, the filing date of PCT application PCT/JP04/19327 to which the instant national stage 371 application claims priority. Acknowledgment is made of applicant's claim to foreign priority under 35 U.S.C. 119(a)-(d). The certified copy of the Japanese application was filed with the USPTO on Jun. 26, 2006.

Claim Objections

Claim 1 is objected to because of the following informalities: the word "principal" should be "principle". Appropriate correction is required.

Claim Rejections - 35 USC § 112 (2nd Paragraph)

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. As written, claim 1 can be

interpreted in at least two ways. In particular, it is unclear whether the phrase "...the adhesive base containing a rubber-system macromolecule having a double bond at least in a principal chain thereof and a nonsteroidal anti-inflammatory drug, and further containing a UVA and/or UVB blocker..." refers to the UVA or UVB blocker being present within the adhesive base or merely present in the patch. Since claims 2-11 depend from claim 1, they are also indefinite. For the purposes of the rejections below, claim 1 will be interpreted to mean a patch containing a UVA or UVB blocker that is not necessarily present in the adhesive base.

Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 10 recites the limitation "...wherein the amount of tackifier added is 10 to 20 mass %." in lines 2-3 of the claim. Claim 10 depends from claim 1. There is insufficient antecedent basis for this limitation in the claim as no tackifier is recited in claim 1. Furthermore, the recitation of 10 to 20 mass % is indefinite since it is unclear to what this mass is relative. For instance, is this mass % relative to the mass of the adhesive base, the support, the entire patch, or some other standard? One of ordinary skill in the art could reasonably construe the claimed mass % to be relative to any of these standards. Since one of ordinary skill in the art could not be expected to make a reasonable distinction in the absence of further definitions and/or guidance in the specification, the metes and bounds of these claims are indefinite.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6, 8, 10, and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Tsuruda *et al.* (International Patent Application Publication No. WO 01/68061; Published Sep. 20, 2001; Reference AC on IDS dated Aug. 3, 2006; U.S. Patent No. 6,924,410 is used herein as an English language translation) (hereinafter Tsuruda *et al.*).

1. Since the WO publication is in Japanese, the U.S. patent to Tsuruda *et al.*, which is the result of the national stage entry of the international application, is relied upon herein as an English language equivalent for all rejections based on WO 01/68061. Column and line numbers refer to the '410 patent.
2. Tsuruda *et al.* disclose patches comprising a backing (i.e. a support) and an adhesive base (abstract; column, line 59 to column 2, line 11). Tsuruda *et al.* teach that the adhesive base of the patches may preferably comprise a styrene-isoprene-styrene block copolymer (i.e. a macromolecule having a double bond at least in a principle chain thereof (column 7, lines 7-14; column 9, lines 4-5). Tsuruda *et al.* also teach the inclusion of a non-steroidal anti-inflammatory drug (NSAID) (column 2, lines 38-41) in the patches of their invention. Furthermore, Tsuruda *et al.* teach the use of an

ultraviolet (UV) screening agent as a stabilizer (i.e. a UVA and/or a UVB blocker) (abstract; column 2, lines 12-33). Thus, Tsuruda *et al.* reads on instant claims 1 and 2.

3. Tsuruda *et al.* teach that the NSAID in the patch is most preferably ketoprofen (column 5, line 15), reading on instant claim 3.

4. Tsuruda *et al.* teach that the ultraviolet screening agents included in the patch preferably comprise, *inter alia*, benzotriazole derivatives (i.e. UVA blockers) (column 2, lines 23-24), reading on instant claim 4. Additionally, it is noted that claims 4 and 5 include the recitation of claim 1 "...containing a UVA blocker *and/or* a UVB blocker...". As such, these claims do not require that a UVA blocker be selected, but rather limit the UVA subset in the case when a UVA blocker is chosen. However, one may still choose to select a UVB blocker instead of a UVA blocker. Since Tsuruda *et al.* teach benzophenone UVB blockers (see below), Tsuruda *et al.* reads on claim 5.

5. Tsuruda *et al.* teach that the ultraviolet screening agents included in the patch preferably comprise, *inter alia*, benzophenone derivatives (i.e. UVB blockers) (column 2, lines 24-29), reading on instant claim 6.

6. Tsuruda *et al.* teach that the adhesive bases of the patches preferably comprise tackifiers such as hydrogenated rosin esters, petroleum resins, and polyterpene resins (i.e. a terpene resin) (column 7, lines 21-24), reading on instant claim 8.

7. As noted above under 112 2nd paragraph rejections, there are two issues of indefiniteness with claim 10. For the purposes of this rejection, the claim has been interpreted to depend from claim 8 and the amount of tackifier is relative to the total amount of the adhesive base. Tsuruda *et al.* teach the addition of tackifiers in an

amount of 10-40% by mass relative to the total amount of the adhesive base (column 9, lines 40-45), reading on instant claim 10.

8. Tsuruda *et al.* teach embodiments wherein the patches (as claimed in instant claim 1) further contain zinc oxide (Example 10, wherein Formulation 6 comprises a styrene-isoprene-styrene block copolymer and a NSAID), reading on instant claim 11.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-6, 8, 10, and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tsuruda *et al.* in view of Honda (U.S. Patent No. 5,637,293; Issued Jun. 10, 1997) (hereinafter Honda).

10. Tsuruda *et al.* teach the patch of instant claim 1 as applied above. Additionally, Tsuruda *et al.* teach the use of a variety of benzotriazole derivatives and other known organic UV screening agents (column 2, lines 20-29; column 2, line 46 to column 3, line 35).

11. Tsuruda *et al.* do not teach the use of the specific UVA blocking agents recited in instant claim 5. Therefore, in the alternative interpretation of claim 5 wherein a UVA blocker must be selected, Honda cures this deficiency.

12. Honda discloses topical preparations comprising UV blocking agents (abstract). The UV blocking agents taught by Honda include both dibenzoylmethane derivatives (column 2, line 60) and benzotriazole derivatives (column 2, lines 61-62). In particular, Honda teaches that either 4-*tert*-butyl-4'-methoxydibenzoylmethane (column 2, line 61) or 2-(2-hydroxy-5-methylphenyl)benzotriazole (i.e. 2-(2'-hydroxy-5'-methylphenyl)benzotriazole), which is taught as an acceptable benzotriazole derivative by Tsuruda *et al.* (Example 1) are acceptable UV blockers in these formulations. Thus, it is clear from the teachings of Honda that 4-*tert*-butyl-4'-methoxydibenzoylmethane and 2-(2'-hydroxy-5'-methylphenyl)benzotriazole are expected to function in the same way.

13. Since Tsuruda *et al.* teach the use of 2-(2'-hydroxy-5'-methylphenyl)benzotriazole as a UVA blocker, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to use 4-*tert*-butyl-4'-methoxydibenzoylmethane as a UV blocker in the patches of Tsuruda *et al.* as both Tsuruda *et al.* and Honda are directed to the same problem of blocking UV light in topical formulations. Because both

compounds have the same function, the artisan would have had a high expectation of obtaining the predictable results of blocking UV light in the topical composition with the 4-*tert*-butyl-4'-methoxydibenzoylmethane.

14. A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, in the absence of evidence to the contrary, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

Claims 1-8, 10, and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tsuruda *et al.* in view of Yasukochi *et al.* (U.S. Patent Application Publication No. 2005/0053646; Filed Jan. 24, 2003) (hereinafter Yasukochi *et al.*).

15. The teachings of Tsuruda *et al.* are presented above. Additionally, Tsuruda *et al.* teach the use of the UV screening agents in an amount from 0.01-20% by mass of the patch backing (column 3, lines 41-45).

16. Tsuruda *et al.* do not teach the use of UV blocking agents in the adhesive base.

17. Yasukochi *et al.* disclose patches comprising pressure sensitive adhesives (abstract). Yasukochi *et al.* teach that the adhesives of these patches may contain a variety of additives including UV-absorbing agents (paragraph [0048]). Yasukochi *et al.* teach that these UV-absorbing agents are preferably used in an amount of 10% or less relative to the total weight of the adhesive composition (end of paragraph [0048]).

18. It is noted that inclusion of the UV screening agent in either the backing or the adhesive base of the patch would have the same stabilizing effect on both the pharmaceutical compound and the rubber-system macromolecules in the adhesive base. Furthermore, adhesive bases comprising UV absorbing agents were known in the art at the time of the invention. Thus, placing the UV blocker in the adhesive base would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention based on the teachings of Tsuruda *et al.* and Yasukochi *et al.* The artisan would have had a high expectation for obtaining the predictable result of preventing UV damage to the skin, pharmaceutical compound, and/or adhesive by including the UV-blocking compound in the adhesive base in an amount of 10% or less, reading on claim 7.

19. A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary

skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, in the absence of evidence to the contrary, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

Claims 1-6 and 8-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tsuruda *et al.*

20. Tsuruda *et al.* teach the patch of instant claim 1 as applied above. Tsuruda *et al.* also teach the use of hydrogenated rosin esters and polyterpene resins as preferred tackifiers (column 7, lines 21-23; column 9, lines 27-29) in the patches of their invention. Tsuruda *et al.* also teach that these tackifying agents may be used in combination (column 9, lines 39-40). Thus, Tsuruda *et al.* teach each element of instant claim 9. However, the difference between Tsuruda *et al.* and instant claim 9 is that Tsuruda *et al.* do not explicitly embody the invention of claim 9 with sufficient specificity to be anticipatory.

21. As set forth in *In re Kerkhoven*, 205 USPQ 1069 (CCPA 1980), "It is *prima facie* obvious to combine two compositions each of which is taught by prior art to be useful for same purpose in order to form third composition that is to be used for very same purpose; the idea of combining them flows logically from their having been individually taught in prior art." In this case, the two tackifiers (a hydorgenated rosin ester and a terpene resin) are known to be useful for the very same purpose. Additionally, Tsuruda *et al.* teach the use of these two tackifiers in combination. Thus, combining them would have been *prima facie* obvious to the ordinary artisan at the time of the invention. The

artisan would have had a high expectation for obtaining the predictable result of a tackifying composition that functions in the very same manner.

22. A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, in the absence of evidence to the contrary, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-4 are directed to an invention not patentably distinct from claims 1, 5, and 6 of commonly assigned 10/552,173. Claims 1-4 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 5, and 6 of copending Application No. 10/552,173. Although the conflicting claims are not identical, they are not patentably distinct from each other because the scope of the '173 claims anticipates that of the instant claims. It is noted that claim 1 of the '173 application recites a polyester backing (i.e. a support), claim 5 of the '173 application recites that the NSAID is ketoprofen, and claim 6 of the '173 application recites a styrene-isoprene-styrene block polymer (i.e. a rubber-system macromolecule having a double bond at least in a principle chain thereof). The overall scope of instant claim 1 is *anticipated* because claim 1 of the '173 application recites a particular species of UVA blocker that is encompassed by the scope of instant claim 1.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned 10/552,173, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

Conclusion

No claims are currently allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin S. Orwig whose telephone number is (571)270-5869. The examiner can normally be reached Monday-Friday 7:00 am-4:00 pm (with alternate Fridays off). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached Monday-Friday 8:00 am-5:00 pm at (571)272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KSO

/Andrew D Kosar/
Primary Examiner, Art Unit 1654